

K221476 PerifitFeb 10, 2023
266 days to decisionK221476 · Product code: **HIR** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k221476/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Perineometer (HIR)
Date received	May 20, 2022
Decision date	Feb 10, 2023
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	X6 Innovations
Location	Paris, FR
Contact	Artem Rodionov
510(k) history	3 submissions · 3 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Lina Kontos

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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